

REMARKS

In response to the Office Action of June 27, 2008, claim 1 is hereby amended and new claims 5 and 6 are added. Claim 1 was rejected under 35 U.S.C. § 101, under 35 U.S.C. § 112, first paragraph, under 35 U.S.C. § 102(b) or in the alternative under 35 U.S.C. § 103(a). Each of these rejections is discussed below.

Rejections under 35 U.S.C. § 101

The Examiner has rejected claim 1 under 35 U.S.C. § 101, as being directed to non-statutory subject matter. Briefly, the Examiner reasons that claim 1 reads on the organism per se as found in nature and thus, is unpatentable. The Examiner suggests that the claim be amended to identify a product that is not found in nature and to indicate the hand of man. In response to this rejection, claim 1 has been amended and new claims 5 and 6 have been added. As amended, claim 1 specifies that the *Candida tropicalis* CJ-FID strain (KCTC10457BP) was isolated and identified as having the nucleotide sequence of SEQ ID NO:1. Support for this amendment can be found in the Specification (page 6, lines 7-16). New claims 5 and 6 are drawn to an isolated culture and strain of *Candida tropicalis* CJ-FID (KCTC10457BP), respectively. Support for new claims 5 and 6 can be found in the Specification (page 5, line 26 - page 6, line 16), which describes the preparation, isolation and identification of a novel culture and strain of *Candida tropicalis* CJ-FID, which has been deposited with the Korean Collection for Type Cultures (KCTC) (accession number KCTC 10457BP). Applicant maintains that the claims as amended are drawn to an isolated product that is not found in nature. As such, Applicant respectfully requests that the Examiner reconsider this rejection.

Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that although it appears that a deposit was made, it is not clear whether the deposit meets all of the criteria set

forth in 37 CFR §§ 1.801-1.809. In response to this rejection, Applicant is submitting a Declaration pursuant to 37 CFR §§ 1.801-1.809, as suggested by the Examiner.

Rejection under 35 U.S.C. § 102(b)/103(a)

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Barbosa *et al.* (1988) *J. of Industrial Microbiology* 3:241-251 in light of Lima (2003) *Brazilian J. of Microbiology* 34(1):1-7. The Examiner reasons that Barbosa *et al.* disclose a *C. guillermondi* strain which produces xylitol which appears to be identical to the presently claimed strain since it produces xylitol under substantially similar process conditions. The Examiner further reasons that Lima *et al.* adequately demonstrate that the strain is properly classified as *C. tropicalis*. From this the Examiner concludes that the instant invention is anticipated by or in the alternative obvious over this combination of references. Applicant respectfully disagrees.

The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984); Alco Standard Corp. v. Tennessee Valley Auth., 1 USPQ2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic v. Genentech Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991, citations omitted). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention either expressly or inherently." Atlas Powder Co. v. Ireco Inc., 190 F.3d. 1342, 1346 (Fed. Cir. (1999) (quoting In re Schreiber, 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

The Examiner bears the burden of establishing a *prima facie* case of obviousness. In determining obviousness, one must focus on the invention as a whole. Symbol Technologies Inc. v. Opticon Inc., 19 USPQ 2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is: "Whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success Both the

suggestion and the expectation of success must be found in the prior art, not the applicant=s disclosure." In re Dow Chemical, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988).

As noted by the Examiner, Barbosa *et al.* teach that several strains of yeast including strains of *C. guilliermondii* and *C. tropicalis* produce xylitol to varying degrees. Applicant however has identified and produced a specific, novel and non-obvious strain of yeast designated as *C. tropicalis* CJ-FID, which produces highly pure xylitol. Additionally, the yield and productivity of xylitol produced by this strain of yeast is higher than any currently known strain of yeast, including that of the strain taught by Barbosa *et al.* While it is not possible to directly compare the strain of *C. tropicalis* taught by Barbosa *et al.* with that of the instant invention, because this reference provides no deposit number, Applicant has nevertheless clearly demonstrated that the strain of the instant invention is not the same strain as that of Barbosa *et al.* Specifically, Applicant has identified *C. tropicalis* CJ-FID as comprising SEQ ID NO: 1 (Specification, page 6, lines 11-13 and sequence listing). Applicant then searched the nucleotide sequences of known strains of *C. tropicalis* in the Gene Bank data base. The nucleotide sequence of the instantly claimed strain was not found in this data bank indicating that this strain of yeast is novel.

Additionally, with reference to Table 2 of the instant invention it can be seen that the presently claimed strain of *C. tropicalis* CJ-FID exhibits a five-fold increase in productivity and greater than 45% higher yield of xylitol than the *C. guilliermondii* FTI 20037 strain taught by Barbosa *et al.* (Specification, page 16. lines 5-14). As such, Applicant maintains that the strain of *C. tropicalis* CJ-FID is neither taught nor suggested by the Barbosa *et al.* reference and thus is not rendered obvious by this reference. Applicant therefore respectfully requests that the Examiner reconsider this rejection.

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The

Appl. No. 10/564,274
Amtd. dated October 23, 2008
Reply to Office Action of June 27, 2008

undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date October 23, 2008

/Rosemary Kellogg/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: KIM *et al.*)
SERIAL NO.: 10/564,274)
FILED: JANUARY 10, 2006)
FOR: NOVEL CANDIDA TROPICALIS CJ-FID(KCTC 10457BP) AND MANUFACTURING METHOD OF XYLITOL THEREBY)
EXAMINER: MARX, I.)
ART UNIT: 1651)
CONFIRM. NO.: 7381)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 CFR §§ 1.801-1.809

Dear Sir:

I, Jin-Soe KIM, do hereby declare as follows:

1. I am an officer of CJ Cheiljedang Corporation, the Assignee of the above-captioned patent application.
2. Claim 1 of the above-captioned patent application has been rejected under 35 U.S.C. § 112, 1st paragraph as being drawn to specific biological materials for which it is not clear that a deposit has been made which meets all of the criteria set forth in 37 CFR §§ 1.801-1.809.
3. As provided in the Specification the *Candida tropicalis* CJ-FID strain of currently amended claim 1 and new claims 5 and 6 has been deposited with the Korean Collection for Type Cultures (KCTC), 52, Oun-dong, Yusong-Ku, Taejon 305-333 Republic of Korea (accession number KCTC 10457BP).
4. All restrictions on the availability to the public of said deposited material will be irrevocably removed upon the granting of a patent.
5. The material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. § 122.
6. The deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least

thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: October 21, 2008

CJ Cheiljedang Corporation

By: J. S. Kim
(Signature by officer)

Print Name: Jin-Soo KIM

Title of Officer: Representative (CEO)